

REMARKS

I. Background

The present Amendment is in response to the Examiner's Office Action mailed October 30, 2006. Claims 1-22 were pending, with claims 4 and 11 being withdrawn. By this amendment, claims 17 and 20 being amended. Claims 1-3, 5-10, and 12-22 are now pending. Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

II. Election/Restriction

Applicants hereby confirm the election of Species 1, directed towards Figures 1-2 and 4-6G, and claims 1-3, 5-10, and 12-22. As such, claims 4 and 11 are withdrawn.

III. Rejections on the Merits

A. Rejections Under 35 U.S.C. § 103

According to the applicable law, a claimed invention is unpatentable for obviousness if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art" 35 U.S.C. § 103(a) (2005); *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966); *MPEP* § 2142. Obviousness is a legal question based on underlying factual determinations including: (1) the scope and content of the prior art, including what that prior art teaches explicitly and inherently; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed

invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18; *In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999). It is the initial burden of the PTO to demonstrate a *prima facie* case of obviousness, which requires the PTO to show that the relied upon references teach or suggest all of the limitations of the claims. *MPEP* § 2142 (emphasis added). To be combined, the references should be analogous. In particular, "[a] prior art reference is analogous if the reference is in the field of applicant's endeavor or, if not, the reference is reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992)(see *MPEP* § 2145).

1. Rejection of Claim 1, 2, 3, 5, 7-10 and 12-22

Claims 1, 2, 3, 5, 7-10 and 12-22 were rejected under 35 U.S.C. § 103 as being unpatentable over *Green et al.* (U.S. Patent No. 5,674,231) in view of *Martinez et al.* (U.S. Patent No. 5,593,412). Applicants respectfully traverse.

Green et al. and *Martinez et al.* are directed to conflicting functional operations that result in it being not obvious to combine their teachings. *Green et al.* is directed to "[a]n apparatus and method . . . for applying a surgical clip to an exterior wall of a blood vessel to at least partially close a hole formed therein" (*Abstract*)(*emphasis added*), while *Martinez et al.* is directed to a "stent delivery method and apparatus" that expands "the balloon and stent to expand the stent to a desired diameter" at the stenotic lesion to increase blood flow through the location of the lesion (*Abstract*). Closing a hole in a blood vessel by applying a clip to an exterior wall of the blood vessel is opposite to opening a vessel by implanting a stent within a lesion within the vessel. As such, *Green et al.* and *Martinez et al.* teach away from each other, i.e., closing a hole in a vessel rather than opening a vessel. Further, because *Green et al.* and *Martinez et al.* are directed to different fields of endeavor, i.e., surgical clips for closing and stents for opening, *Green et al.* and *Martinez et al.* are not within the same field of endeavor and as such should not be combined.

In addition to the above, the underlying purposes of the *Martinez et al.* devices teach away from combining its teaching with *Green et al.* Prior stent on a balloon assemblies "cause[d] trauma to the vessel into which . . . [the assembly was] inserted as it track[ed] through the vessel" (Col. 4, ll. 24-28). To solve this problem, and as taught by *Martinez et al.*, a sheath

was placed around the stent. This would reduce trauma to the vessel as it is moved from outside the body to the lesion through the anatomy of the patient.

Unlike the device of *Martinez et al.*, the device of *Green et al.* passes from outside the body to just inside the blood vessel, as illustrated in Figure 11. The vascular hole closure device doesn't need to be navigated through the vessel to a stenotic lesion that can be distant from the access hole in the vessel. Inclusion of the sheath of *Martinez et al.* in the device of *Green et al.* would not be necessary because the device of *Green et al.* is deployed into "the interior lumen 102 of blood vessel 104 through a conventional cannula 100, which had previously been extended through hole 106 formed in the wall of blood vessel 104 during the catheterization procedure" (Col. 7, ll. 19-23)(emphasis added). The cannula provides protection to the surrounding tissue until the clip is to be deployed. As such, it would not be necessary to include the protective sheath of *Martinez et al.* with the device of *Green et al.* since the cannula provides the desired protection.

For the reasons stated above, Applicants respectfully submit that the scope and content of *Green et al.* and *Martinez et al.*, nor the level of ordinary skill in the prior art, teaches or suggests combining the device of *Martinez et al.* with the device of *Green et al.* In fact, Applicants respectfully submit that one of ordinary skill looking to modify a device that "at least partially close a hole" in a vessel from the exterior would not look to devices for opening a vessel from the interior. As such, Applicants respectfully request withdrawal of the rejection of claims 1, 2, 3, 5, 7-10 and 12-22 under 35 U.S.C. § 103.

2. Rejection of Claim 6 under 35 U.S.C. § 103

Claim 6 was rejected under 35 U.S.C. § 103 as being unpatentable over *Green et al.* in view of *Martinez et al.* and further in view of *Kammer et al.* (U.S. Patent No. 5,868,755). Since claim 6 depends from independent claim 1, and since *Kammer et al.* does not teach or suggest the invention claimed in independent claim 1 or aid with the combination of *Green et al.* and *Martinez et al.*, Applicants respectfully submit that for the same reasons as those stated above with respect to the combination of *Green et al.* and *Martinez et al.* the rejection of dependent claim 6 should be withdrawn.

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will

be appreciated, however, that this should not be construed as Applicants acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicants reserve the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicants specifically request that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

CONCLUSION

In view of the foregoing, Applicants believe the claims provided in the claim listing are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 30th day of January, 2007.

Respectfully submitted,

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